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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,548	09/30/2005	Kunio Kamata	279057US0PCT	3923

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
09/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/551,548	KAMATA ET AL.	
	Examiner	Art Unit	
	BAO LI	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-15,20 and 21* is/are rejected.

7)☒ Claim(s) *17-19 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/8/2008, 11/30/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The response and amendment filed in on June 19, 2008 have been acknowledged. Claims 1-9 have been canceled. New claims 10-23 are pending.

Information Disclosure Statement

1. The translation of a foreign document filed on 11/30/2005 has been provided and considered.

2. All of the documents filed with IDS on 11/30/2005 have been considered and initialed.

3.

Priority

4. English translated foreign priority document filed on June 19, 2008 has been acknowledged. The objection has been removed.

5.

Withdrawn Claims objections

6. The objection of claims 4 and 6-9 under 37 CFR 1.75(c) has been removed in view of the cancellation of claims 4 and 6-9.

7.

Withdrawn Claim Rejections - 35 USC § 102

8. All rejections of claims under ***35 USC § 102 (b)*** made in the previous office action have been moot in view of the new ground rejections due to the amendment filed in on June 19, 2008, in which all previous pending claims were canceled.

9.

New Grounds of Rejections

Because Applicants have cancelled all previous pending claims, all rejections made in the previous office action are moot in view of new grounds of rejections necessitude by Applicants' amendment.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for having a method using an anti-norovirus antibody to detect norovirus in a biological specimen, does not reasonably provide enablement for having a method using an anti-Norovirus antibody to detect Sapovirus in a biological specimen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

12. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would be undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Factors to be considered in determining whether undue experimentation is required for the broad scope of claims are summarized below: 1). The nature of the invention, 2). the state of the prior art, 3). the relative skill of those in the art, 4). the amount of direction or guidance disclosed in the specification, 5). the presence or absence of working examples, 6). the predictability or unpredictability of the art, 7). the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

13. The nature of the invention is that Applicants have develop a simple method for detecting Norovirus in a specimen using a alkaline buffer at pH 9-10 to coat an antibody against Norovirus , wherein the buffer further comprises surfactant. The specimen is also prepared in such alkaline buffer further comprises the surfactant, a water-soluble polymer and 1-8% salt in mass. The assay conducted in such alkaline buffered condition increase the sensitivity of the detection and produces more significant signals for the binding compared with the condition using a buffer having a neutral pH at 7.2. The detection of Norovirus is required using anti-Norovirus antibody detection of Sapovirus require using anti-Sapovirus antibody.

14. However, the scope of the claim 22 is drawn to a method using anti-Norovirus to detect Sapovirus in a specimen.

15. The state of art teaches that Norwalk (Norvirus) and Sapovirus are two different genus of positive strain RNA virus of *Caliciviridae* family (ICTVdB Index of Viruses published on line by June 2002). They are genetically and antigenically distinct as evidenced by Martinez et al. (J. Med. Virol. 2001, Vol. 67, pp. 289-298). The state of art also teaches that antigenically, Sapporo-like human calicivirus (HuCVs are distinct from the caliciviruses, such as Norwalk virus (NV) and Snow Mountain agent (SMA)-like viruses by enzyme immune assays (ELISA) as evidenced by Jiang et al. (Arch Virol. 1997, Vol. 142, pp. 1813-1827, see page 1813-1824). Kitamoto et al. also teach that there are many monoclonal antibodies against genotype I (GI), genotype II (GII) of Noroviruses, and an antibody against Sapovirus, but none of disclosed antibodies can cross-recognize GI or GII with Sapovirus (See Table 1). Therefore, it is unpredictable that a Norovirus antibody can be used for a deferential diagnosis of a sapovirus from a Norrovirus.

16. The specification only teaches that an antibody used for the Norovirus detection is monoclonal NV3912 capable of recognizing Norovirus genotype I (GI) and monoclonal antibody NS14 capable of broadly recognizing Norovirus genotype II (GII). The specification does not teach such antibodies capable of detecting a Sapovirus. The specification provides no guidance for selecting an anti-Norovirus antibody that is capable of deferential diagnosis of a Sapovirus infection from a Norovirus infection. There is no teaching about a common antigen epitope shared by Norovirus and Sapovirus in the specification. Therefore, the current Application does not provide sufficient evidence to support the claim 22. Consequently, no direction or guidance in the current specification can assist one skilled in the art using the claimed method to have a deferential detecting a Sapovirus with an anti-Norovirus antibody.

17. Since specification lacks support of the claimed invention. And sate of art does not recognize there is such antibody capable of differentially diagnosis of a Sapovirus from a Norovirus infection in a Specimen, it is concluded that undue experimentation would be required to enable the scope of the intended claim.

18.

19. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention. Because Application as it originally filed does not describe a method using an anti-Norovirus antibody to detect a Sapovirus infection in a specimen.

20. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably concluded that the inventor had possession of the claimed invention. The possession of claimed invention can be shown by describing the claimed invention with all of its limitations in the specification including drawing or description of an actual reduction to practice. The written description may arise in the following situations: a). The claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention; b). The claimed invention as a whole may not adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art; and c). The invention is described solely in terms of a method of its making coupled with its function and there is no described or art recognized correlation or relationship between the structure of the invention and its function etc.

21. In the instant case as described in the enablement rejection above, specification only teaches that an antibody used for the Norovirus detection is monoclonal NV3912 capable of recognizing Norovirus genotype I (GI) and monoclonal antibody NS14 capable of broadly recognizing Norovirus genotype II (GII). The specification does not teach said antibodies capable of detecting a Sapovirus. The specification provides no teaching and guidance about selecting an anti-Norovirus antibody capable of deferential diagnosis of a Sapovirus infection from a Norovirus infection. Therefore, the current Application does not provide sufficient evidence to support the claim 22. Consequently, no direction or guidance in the current specification can assist one skilled in the art using the claimed method to have a deferential detecting a Sapovirus with an anti-Norovirus antibody.

22. Moreover, the state of art teaches that Norwalk (Norvirus) and Sapovirus are genetically and antigenically distinct (ICTVdB Index of Viruses published on line by June 2002). The state of art teaches that Sapporo-like human calicivirus (HuCVs are distinct from the caliciviruses, such as Norwalk virus (NV) and Snow Mountain agent (SMA)-like viruses. Antigenically,

Sopporo-like HuCVs are distinct from the NV- and SMA-like HuCVs by enzyme immune assays (ELISA) as evidenced by Jiang et al. (Arch Virol. 1997, Vol. 142, pp. 1813-1827, see page 1813-1824). There are no antibodies against genotype I (GI) and genotype II (GII) of Noroviruses (Norwalk viruses) know in the art that is capable of recognizing Sapovirus rather not recognize Norovirus itself as evidenced by Kitamoto et al. (J. Clin. Microbiol., 2002 Jul;40(7):2459-65).

23. As discussed above, claim 22 fails to all three criteria of writen description cited above.

24. Therefore, the claimed invention in claim 22 has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention in claim 22.

25.

Claim Rejections - 35 USC § 112

26. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

27. Claims 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to detect the binding. The specification lists many essential steps of adding a labeled antibody to develop the binding signal.

28.

Claim Rejections - 35 USC § 102

29. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

30. Claims 10-14 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardy et al. (Virology, 1996, Vol. 217, pp. 252-261).

31. Hardy et al. describe an assay for detecting a Norwalk virus., i.e. antigen-capture ELISA (MACE) assay that uses a composition comprising a monoclonal antibody (MAb) against

Norwalk virus in a Carbonate-bicarbonate buffer at pH 9.6 diluent. This meets the limitation of claims 10 and 13.

32. The assay is processed by first mobilizing said MAb in the said alkaline buffer onto the microtiter plate, adding a biological specimen to the plate and incubating the plate for a period time. At this point, the reaction is considered as a composition comprising an antibody against as Norovirus and a possible Norovirus or Sapovirus infection. Following a washing step to remove the unbound specimen, another polyclonal guinea pig anti-recombinant Norwalk virus particle (rNV) polyclonal antiserum is added to the antigen/antibody complex for incubation a period of time. Finally, a horse radish peroxides-conjugated goat anti-guinea pig immunoglobulin is added to the antibody/antigen/antibody sandwich for the color matrix development (page 253 last paragraph), the anti-Norovirus antibody is considered to be indirectly labeled with a horse radish peroxides. Since claims 14 and 21 do not limit the labeling as directly or indirectly, the disclosure of this assay further meets the limitation of claims 10, 13, 14 and 20-22,

33. Moreover, Hardy et al. also disclose preparation of a recombinant Norwalk virus particle composition in an alkaline 10 mM Tris buffer (Tris buffer is one of the Good's buffers in light of the teaching by wikipedia.org/wiki/Good's_buffers, pages 1-2, Sept. 9, 2008), pH 9.0. The composition is used for an immune electron microscope (IEM) assay by adding anti-rNV antibody into the mixture comprising 5 or 10 μg of said rNV in said Tris alkaline buffer. To this context, the reaction mixture is considered to be a composition comprising rNV and anti-Norovirus antibody in a Tri-Buffer pH 9.0 (page 235, paragraphs 3 and 4). This disclosure further meets limitation of claims 10-12, 20 and 22.

34. Therefore, the cited reference anticipates claims 10-14, 20 and 21.

35.

36. Claims 10, 13, 14, 16 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (J. Med. Virol, 2000, Vol. 62, pp.233-238) or Hale et al. (Clinical and Diagnostic Virology 1996, Vol. 5, pp. 27-35).

37. Kobayashi et al. and Hale et al. both describe an assay for detecting a Norwalk virus. The assay is an antigen-capture assay of ELISA (MACE). The assay comprises using a composition of a rabbit antiserum against a Norwalk virus diluted in a 0.1 M Carbonate-bicarbonate buffer at pH 9.6. The rabbit antiserum comprises other rabbit globulins in addition to the specific anti-

Norovirus antibody. Therefore, the composition meets the limitations of claims 10, 13, 16. The assay is performed by coating 96-well microtiter plates with said antiserum in said alkaline buffer first, and then incubating it with a biological specimen. After incubation, the plate was washed to removed the non-bound substance, and added with another polyclonal guinea pig antibody against recombinant Norwalk virus particle. Finally, a horse radish peroxides-conjugated goat anti-guinea pig immunoglobulin is added to the antibody/antigen/antibody sandwich complex, herby the anti-Norovirus antibody is indirectly labeled (page 234 for Kabayoshi et al). Kobayashi et al. do not teach using a composition comprising an anti-Sapporo virus antibody (page 234 for Kabayoshi et al. and page 29 by Hale et al.). Taking together, the disclosures of the references anticipate claims 10, 13, 14, 16 and 20-21.

38.

Claim Rejections - 35 USC § 103

39. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

40. Claims 10, 13, 15-16, 20-21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. (J. Med. Virol, 2000, Vol. 62, pp.233-238) and Kitamoto et al. (J. Clin. Micro. 2002, Vol. 40, No. 7, pp. 2459-2465).

41. Kobayashi et al. describe an assay for detecting a Norwalk virus. The assay is an antigen-capture assay of ELISA (MACE). The assay comprises using a composition of a rabbit antiserum against a Norwalk virus diluted in a 0.1 M Carbonate-bicarbonate buffer at pH 9.6. The assay is performed by coating 96-well microtiter plates with said antiserum in said alkaline buffer first, and then incubating it with a biological specimen. After incubation, the plate was washed to removed the non-bound substance, and added with another polyclonal guinea pig antibody against recombinant Norwalk virus particle. Finally, a horse radish peroxides-conjugated goat anti-guinea pig immunoglobulin is added to the antibody/antigen/antibody sandwich complex,

herby the anti-Norovirus antibody is indirectly labeled (page 234 for Kabayoshi et al). Kobayashi et al. do not teach using a composition comprising an anti-Sapporo virus antibody.

42. Kitamoto et al. disclose two monoclonal antibodies SV68 and SV137 specifically recognizing Sapporo virus and several other monoclonal antibodies specifically recognizing the Noroviruses in a similar enzyme-linked immunological assay. These antibodies are very specific that can only detect Sapporo virus and Noroviruses respectively.

43. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references and to use the specific anti-sapporo virus disclosed by Kitamoto et al. in the assay developed by Kobayashi et al. to detect either Sapporo virus with an expectation of success. Absence of unexpected results to the contrary, the claimed invention as a whole is prima facie obvious absence unexpected results.

44.

45. Claims 10-15 and 20-21, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy et al. (Virology, 1996, Vol. 217, pp. 252-261) and Kitamoto et al. (J. Clin. Micro. 2002, Vol. 40, No. 7, pp. 2459-2465).

46. Hardy et al. describe an assay for detecting a Norwalk virus, i.e. antigen-capture ELISA (MACE) assay that uses a composition comprising a monoclonal antibody (MAb) against Norwalk virus in a Carbonate-bicarbonate buffer at pH 9.6 diluent. This meets the limitation of claims 10 and 13.

47. The assay is processed by first mobilizing said MAb in the said alkaline buffer onto the microtiter plate, adding a biological specimen to the plate and incubating the plate for a period time. At this point, the reaction is considered as a composition comprising an antibody against as Norovirus and a possible Norovirus or Sapovirus infection. Following a washing step to remove the unbound specimen, another polyclonal guinea pig anti-recombinant Norwalk virus particle (rNV) polyclonal antiserum is added to the antigen/antibody complex for incubation a period of time. Finally, a horse radish peroxides-conjugated goat anti-guinea pig immunoglobulin is added to the antibody/antigen/antibody sandwich for the color matrix development (page 253 last paragraph), the anti-Norovirus antibody is considered to be indirectly labeled with a horse radish peroxides. Since claims 14 and 21 do not limit the labeling as directly or indirectly, the disclosure of this assay further meets the limitation of claims 10, 13, 14 and 20-22,

48. Moreover, Hardy et al. also disclose preparation of a recombinant Norwalk virus particle composition in an alkaline 10 mM Tris buffer (Tris buffer is one of the Good's buffers in light of the teaching by wikipedia.org/wiki/Good's_buffers, pages 1-2, Sept. 9, 2008), pH 9.0. The composition is used for an immune electron microscope (IEM) assay by adding anti-rNV antibody into the mixture comprising 5 or 10 μg of said rNV in said Tris alkaline buffer. To this context, the reaction mixture is considered to be a composition comprising rNV and anti-Norovirus antibody in a Tri-Buffer pH 9.0 (page 235, paragraphs 3 and 4). This disclosure further meets limitation of claims 10-12, 20 and 22.

49. Hardy et al. do not teach using anti-Sapovirus antibody in the composition.

50. Kitamoto et al. disclose two monoclonal antibodies SV68 and SV137 specifically recognizing Sapporo virus and several other monoclonal antibodies specifically recognizing the Noroviruses in a similar enzyme-linked immunological assay. These antibodies are very specific that can only detect Sapporo virus and Noroviruses respectively.

51. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the recited references and to use an anti-sapovirus antibody disclosed by Kitamoto et al. for specifically diagnosis of Sapovirus in a specimen in the assay developed by Kobayashi et al. with an expectation of success. Therefore, absence of unexpected results to the contrary, the claimed invention as a whole is prima facie obvious absence unexpected results.

52.

Conclusion

No claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAO LI whose telephone number is (571)272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li, M.D/
Examiner, Art Unit 1648